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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,055	06/25/2003	Charles E. Hart	00-79D1	3796

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EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

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DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,055	HART ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 (in part), 10, 11, 13-16 (in part), are drawn to a method of reducing extracellular matrix (ECM) production comprising administration of anti-zvegf4 antibodies, classified in class 514, subclass 2.

II. Claims 1-9 (in part), 12, 13-16 (in part) are drawn to a method of reducing ECM production by administration of inhibitory polynucleotides, classified in class 514, subclass 44.

III. Claims 1-8 (in part), 13-16 (in part) are drawn to a method of reducing ECM production comprising administration of inhibitors of zvegf4 activiation, classified in class 514, subclass 2.

IV. Claims 1-8 (in part), 13-16 (in part), are drawn to a method of reducing ECM production comprising administration of mitogenically inactive receptor binding variants of zvegf4, classified in class 514, subclass 2.

V. Claim 17, in part, is drawn to a method of reducing metastasis, comprising administration of anti-zvegf4 antibodies, classified in class 514, subclass 2.

VI. Claim 17, in part, is drawn to a method of reducing metastasis, comprising administration of inhibitory polynucleotides, classified in class 514, subclass 44.

VII. Claim17, in part, is drawn to a method of reducing metastasis, comprising administration of inhibitors of zvegf4 activation, classified in class 514, subclass 2.

VIII. Claim 17, in part, is drawn to a method of reducing metastasis, comprising administration of mitogenically inactive receptor binding zvegf4 variants, classified in class 514, subclass 2.

IX. Claims 18-21 (in part), 22, 23 and 25-32, are drawn to a method of treating a hyperproliferative disorder comprising administration of anti-zvegf4 antibodies, classified in class 514, subclass 2.

X. Claims 18-21, in part, are drawn to a method of treating a hyperproliferative disorder comprising administration of inhibitors of zvegf4 activation, classified in class 514, subclass 2.

XI. Claims 18-21 in part, are drawn to a method of treating a hyperproliferative disorder comprising administration of mitogenically inactive receptor binding zvegf4 variants, classified in class 514, subclass 2.

XII. Claims 18-21, in part, are drawn to a method of treating a hyperproliferative disorder comprising administration of inhibitory polynucleotides, classified in class 514, subclass 44.

XIII. Claim 24, in part, is drawn to a method of reducing stellate cell activation comprising administration of anti-zvegf4 antibodies, classified in class 514, subclass 2.

XIV. Claim 24, in part, is drawn to a method of reducing stellate cell activation comprising administration of mitogenically inactive receptor binding zvegf4 variants, classified in class 514, subclass 44.

XV. Claim 24, in part, is drawn to a method of reducing stellate cell activation comprising administration of inhibitory polynucleotides, classified in class 514, subclass 44.

Groups I-IV, V-VIII, IX-XII and XIII-XV are drawn to methods for treatment of different conditions, therefore the patient populations are not the same. Groups I-IV are drawn to reducing ECM production and groups V-VIII are drawn to methods of reducing metastases; a search on reducing ECM production is not coextensive with a search on reducing metastases. Groups IX-XII are drawn to methods of treating a hyperproliferative disorder; a search on patients with hyperproliferative disorders would not be coextensive with one on reducing ECM production. Groups XIII-XV are drawn to methods of reducing stellate cell activation; a search on stellate cell activation would not be coextensive with one on reducing ECM production. Groups V-VIII are drawn to methods of reducing metastases; a search on reducing metastases would not be coextensive with treatment of a hyperproliferative disorder (groups IX-XII). Likewise, a search for reducing metastases would not be coextensive with one on stellate cell activation (groups XIII-XV). Finally a search on the treatment of hyperproliferative disorders would not be coextensive with one on stellate cell activation. Because all of the groups described above are drawn to different conditions and therefore, different patient populations, a search and examination of all four methods in one patent application would result in an undue burden, since the searches for the different patient populations are not co-extensive, and the subject matter is divergent.

Furthermore, the Groups are drawn to different methods that use different substrates. Groups I, V, IX and XIII are drawn to different methods that use anti-zvegf4 antibodies. Groups II, VI, XII and XV are drawn to different methods that use inhibitory polynucleotides. The searches for antibodies and polynucleotides are not coextensive because antibodies are IgG molecules that comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions. Polypeptides, like the antibodies used in groups I, V, IX and XIII are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. These are different substrates with different activities and the search and examination of both would result in an undue burden, since the searches are not co-extensive, and the subject matter is divergent.

A search for anti-zvegf4 antibodies used in groups I, V, IX and XIII is not coextensive with a search for the inhibitors of zvegf4 activity of groups III, VIII and X because any relationship between polypeptides and antibodies is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. These are different substrates with different activities and the search and examination of

both substrates would result in an undue burden, since the searches are not co-extensive, and the subject matter is divergent.

Likewise, a search for anti-zvegf4 antibodies used in groups I, V, IX and XIII is not coextensive with a search for the mitogenically inactive receptor binding zvegf4 variants used in groups IV, VIII XI and XIV because any relationship between polypeptides and antibodies is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. These are different substrates with different activities and the search and examination of both substrates would result in an undue burden, since the searches are not co-extensive, and the subject matter is divergent.

Groups III, VII and X are drawn to different methods that use inhibitors of zvegf4 activation, and the search would not be coextensive with the polynucleotides used in groups II, VI, XII and XV because polypeptides are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. These are different substrates with different activities and the search and examination of both substrates would result in an undue burden, since the searches are not co-extensive, and the subject matter is divergent.

Groups IV, VIII, XI and XIV are drawn to methods that use mitogenically inactive receptor binding zvegf4 variants. A search for mitogenically inactive receptor binding zvegf4 variants is not coextensive with a search for inhibitory polynucleotides because polypeptides are composed of amino acids, and polynucleotides (groups II, VI, XII and XV), which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. These are different substrates with different activities and the search and examination of all four substrates would result in an undue burden, since the searches are not co-extensive, and the subject matter is divergent.

Finally, a search for inhibitors of zvegf4 activation used in groups III, VII, and X is not coextensive with a search for mitogenically inactive receptor binding variants of zvegf4 (IV, VIII, XI and XIV) because they are different proteins with different functions; the former inhibit activation of zvegf4 and the latter are receptor antagonists. These are different substrates with different activities and the search and examination of both would result in an undue burden, since the searches are not coextensive, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and different searches are required for Groups I-XV, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to the following patentably distinct species of the claimed invention: Tissue/cell types.

I. Tissue/cell types

I-a. prostate

I-b. mesangial

I-c. epithelial

I-d. endothelial

I-e. smooth muscle

I-f. fibroblast

I-g. osteoblast

I-h. osteoclast

I-i. neuronal

I-j. stromal

I-k. stellate

I-l. interstitial

I-m. kidney

I-n. liver

I-o. bone

The species represent different tissue and cell types with different physiologies; success with one does not render success with another obvious.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 5, 9-14, 17, 18 and 22-32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christina Borgeest, Ph.D.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER